REMARKS

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herewith.

Claims 20-111 are currently pending. Claims 111-116 have been newly added. Support for these claim is found throughout the specification and claims as originally drawn.

The Office Action required restriction under 35 U.S.C. §121 from among one of the following groups of inventions:

Group I: Claims 20-29, drawn to a method comprising determining the sequence of an HIB envelope gene V3 region;

Group II: Claims 30-32 and 54-110, drawn to a method comprising determining the ratio of HIV using the CXCR4 coreceptor to HIV using the CCR5-coreceptor;

Group III: Claims 33-50, drawn to a method comprising a fusion assay;

Group IV: Claims 51-53, drawn to a composition comprising one or more cells comprising an HIV Tat-activatable reporter gene construct, an HIV envelope gene variant cloned from an infected patient, a constitutively active tat gene, and an HIV envelope-compatible coreceptor.

In addition, the Office Action requires a species election between: (A) source of patient sample: (1) peripheral blood; (2) genital secretions (3) cerebrospinal fluid; and (B) the antiretroviral therapy of: (4) claim 89; (5) claim 90; (6) claim 91; (7) claim 92.

Group II, claims 30-32 and 54-110, drawn to a method comprising determining the ratio of HIV using the CXCR4 coreceptor to HIV using the CCR5-coreceptor, is hereby provisionally elected, with traverse, for further prosecution in this application. Applicants further provisionally elect, with traverse, the following further species elections: peripheral blood as the source of patient sample, and the antiretroviral therapy of claim 89.

Applicants further assert that newly added claim 111, drawn to a method of monitoring the efficacy of antiretroviral therapy in a patient comprising quantitating the usage of CXCR4 and CCR5 is covered by the present election.

Applicants reserve the right to file divisional applications to non-elected subject matter. Reconsideration and withdrawal of the requirement for restriction and the requirement for election of species are respectfully requested in view of the remarks herewith.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP §803. Second, the examiner must examine the entire application on the merits "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.* Accordingly, the MPEP directs the examiner to search and examine an entire application regardless of whether it includes distinct or independent inventions where no serious burden is placed on the examiner by the search and/or examination.

Accordingly, Applicants request modification of the Restriction Requirement to rejoin Groups I, II, III, and IV.

In the alternative, Applicants request modification of the Restriction Requirement such that the claims of Group II are rejoined with, and thus searched and examined together with, the claims of Group I, since the claims of these groups taken together as originally filed and presented herein represent a web of knowledge and continuity of effort that merits search and examination as a single invention. The invention as disclosed in the present application in Groups I and II relate broadly to diagnostic methods for determining which antiretroviral therapy is most appropriate for a patient and whether such therapy is effective. Accordingly, it is respectfully asserted that each of the claims of the present application fall within the same inventive concept and thus, search and examination of both groups of claims would not be unduly burdensome on the part of the Examiner.

In another alternative, Applicants further request modification of the Restriction Requirement such that the claims of Group II are rejoined with, and thus searched and examined together with, the claims of Group IV since the claims of these Groups share the identical search classification.

Groups II and IV of the classification of the Office Action are commonly classified under class 435, subclass 4. The fact that these Groups are identically classified necessarily indicates that search and examination of the claims in these Groups would be coextensive and thus, there would not be an undue burden placed on the Examiner. Therefore, in another alternative, it is respectfully submitted that Groups II and IV should be subject to rejoinder.

Further, in view of the requirement for an election of species, whereby the Examiner requires an election of a source of patient sample (peripheral blood, genital secretions, or cerebrospinal fluid), and of antiretroviral therapies, the Examiner is respectfully requested to

review MPEP §803.02 which states "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." Furthermore, in view of MPEP §803, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

Applicant's claims are generally directed to diagnostic methods of determining CXCR4 and CCR5 coreceptor usage. Turning first to the source of patient sample election, the instant application contains claims directed to *only one of three* sources of patient samples: peripheral blood, genital secretions, or cerebrospinal fluid. Thus sufficiently few species are under consideration in the present application, such that a search and examination of all the species at one time would not impose a serious burden on the examiner. Furthermore, there is a disclosure of the relationship between the claimed species of source of patient sample. The specification discloses on page 12, line 13:

> Clinical specimens comprising tissues and/or fluids from HIV-infected patients can be utilized for cloning envelope genes of interest. Advantageously, patient-derived virus can be obtained from sites in addition to peripheral blood, particularly those sites from which cultured virus cannot be obtained. For example, while circulating macrophages and $CD4^+$ T cells are the dominant reservoir of HIV-1, viral populations distinct from those in the peripheral blood exist in many tissue reservoirs, including the genital mucosa and lymphoid tissue.

Such disclosure makes it clear that the species claimed are closely related.

Further still, the claims are not broken into separate classifications in the Office Action, on the basis of which species is claimed. It can therefore be assumed that the classification of all the claims into a single group was made considering each of the species, such that the search of any species would be coextensive with and include the remaining species.

For all of the foregoing reasons, search and examination of all claimed species of source of patient sample would not place any undue burden on the Office. Accordingly, reconsideration and withdrawal of the requirement for election of species based on patient sample source is respectfully requested.

Turning to the antiretroviral therapy election, the instant application generally contains claims directed to a method of monitoring the effectiveness of different kinds of antiretroviral

therapies. Claim 89 recites *kinds* of antiretroviral therapies, which includes nucleoside analogue reverse transcriptase inhibitors, while claims 90-92 each recite a *specific* nucleoside analogue reverse transcriptase inhibitor, including 3TC, AZT, or nevirapine. Therefore, claims 90-92 are encompassed by claim 89 and accordingly, search and examination of all claimed species of antiretroviral therapy would not place any undue burden on the Office. Accordingly, reconsideration and withdrawal of the requirement for election of species based on antiretroviral therapy is respectfully requested.

In view of the remarks herein, enforcing the present Restriction Requirement would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met. Indeed, the search and examination of each commonly classified Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal, or at least modification, of the Restriction Requirement, such that, at the least the claims of Groups I, II, and IV are examined together.

CONCLUSION

Reconsideration and withdrawal, or modification of the restriction requirement, and a prompt and favorable examination on the merits, is respectfully requested.

Respectfully submitted,
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